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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/763,539	01/26/2004	Stephen J. Karlik	002010-854

## CONFIRMATION NO. 9237

21839  
BURNS DOANE SWECKER & MATHIS L L P  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

## FORMALITIES LETTER



\*OC000000015873445\*

Date Mailed: 04/26/2005

## NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

## FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Page(s) 346 of the specification (description and claims).

I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$400.00 petition fee (37 CFR 1.17(f))) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if is determined that the item(s) was received by the USPTO.

II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$400.00 petition fee (37 CFR 1.17(f)) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(f)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted items(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) OR (b).** In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the

references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes . Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

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*A copy of this notice **MUST** be returned with the reply.*

*Bleale*

Office of Initial Patent Examination (703) 308-1202  
PART 2 - COPY TO BE RETURNED WITH RESPONSE



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Steve J. Karlik et al.

Application No.: 10/763,539

Filing Date: January 26, 2004

Title: COMPOSITION FOR AND TREATMENT OF DEMYELINATING DISEASES AND PARALYSIS BY  
ADMINISTRATION OF REMYELINATING AGENTS

Group Art Unit:

Examiner:

Confirmation No.: 9237

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

A Petition for Extension of Time is also enclosed.

Terminal Disclaimer(s) and the  \$65.00 (2814)  \$130.00 (1814) fee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.

Also enclosed is/are Copy of page 346 of the specification as-filed on January 26, 2004; copy of date-stamped postcards; and copy of Notice of Omitted Item(s) in a Nonprovisional Application

Small entity status is hereby claimed.

Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the  \$395.00 (2801)  \$790.00 (1801) fee due under 37 C.F.R. § 1.17(e).

Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.

Applicant(s) previously submitted \_\_\_\_\_

on \_\_\_\_\_, for which continued examination is requested.

Applicant(s) requests suspension of action by the Office until at least \_\_\_\_\_, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

No additional claim fee is required.  
 An additional claim fee is required, and is calculated as shown below.

<b>AMENDED CLAIMS</b>					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims		MINUS =	0	x \$50.00 (1202) =	\$ 0.00
Independent Claims		MINUS =	0	x \$200.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$360.00 (1203)					
Total Claim Amendment Fee					
<input type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					
<b>TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT</b>					
<b>\$ 0.00</b>					

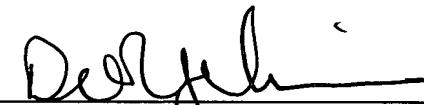
A check in the amount of \_\_\_\_\_ is enclosed for the fee due.  
 Charge \_\_\_\_\_ to Deposit Account No. 02-4800.  
 Charge \_\_\_\_\_ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By

  
Deborah H. Yellin  
Registration No. 45,904

Date: June 9, 2005



Patent  
Attorney's Docket No. 002010-854

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
Steve J. Karlik et al. ) Group Art Unit: Unassigned  
Application No.: 10/763,539 ) Examiner: Unassigned  
Filed: January 26, 2004 ) Confirmation No.: 9237  
For: COMPOSITION FOR AND )  
TREATMENT OF DEMYELINATING )  
DISEASES AND PARALYSIS BY )  
ADMINISTRATION OF )  
REMYELINATING AGENTS )

**RESPONSE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION  
FILED UNDER 37 C.F.R. § 1.53(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Notice of Omitted Item(s) in a Nonprovisional Application Filed Under 37 C.F.R. § 1.53(b), dated April 26, 2005, Applicants submit the following:

Page 346 of the specification that was purportedly omitted from the application when filed on January 26, 2004.

Applicants state that the specification, as filed, on January 26, 2004 did contain page 346, which is attached hereto for the convenience of the office. A copy of the stamped postcards, to this effect, dated January 26, 2004 is also attached showing the complete specification was acknowledged as filed. In the event there are any questions pertaining to this Response, the undersigned can be reached at the number below.

No fee is believed necessary. However, the Director is hereby authorized to charge any appropriate fees that may be required by this paper, and credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: June 9, 2005

By:   
Deborah H. Yellin  
Registration No. 45,904

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

VA 751520.1



- 3.35 (m, 1H), 3.26 - 3.19 (m, 1H), 3.12 - 2.97 (m, 8H), 2.06 - 2.03 (m, 1H), 1.66 - 1.57 (m, 3H), 1.26 (d, 6H).

<sup>13</sup>C NMR (CDCl<sub>3</sub>): δ 170.50, 170.40, 154.90, 153.60, 150.70, 150.30, 133.30, 132.90, 130.10, 125.00, 121.80, 121.80, 118.50, 112.80, 69.60, 62.20, 53.20, 49.60, 37.10, 36.60, 36.30, 30.10, 24.20, 21.59, 21.56.

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#### Example 184

##### Synthesis of

##### *N*-(3,4-Difluorobenzenesulfonyl)-L-prolyl-4-(*N,N*-dimethylcarbamyloxy)phenylalanine

10

The title compound was prepared from the product of Example 183 using the procedure described in Method 7.

NMR data was as follows:

<sup>1</sup>H NMR (CD<sub>3</sub>OD): δ 8.10 (d, 1H), 7.84 - 7.77 (m, 1H), 7.69 - 7.65 (m, 1H), 7.53 - 7.45 (m, 1H), 7.28 (d, 2H), 7.02 (d, 2H), 4.72 - 4.68 (m, 1H), 4.19 - 4.16 (m, 1H), 3.43 - 3.39 (m, 1H), 3.31 - 3.21 (m, 2H), 3.13 - 3.05 (m, 4H), 2.97 (s, 3H), 1.86 - 1.61 (m, 4H).

<sup>13</sup>C NMR (CD<sub>3</sub>OD): δ 174.2, 174.1, 164.7, 156.9, 154.9, 152.0, 151.6, 135.8, 135.6, 131.6, 129.7, 122.9, 119.7, 118.8, 63.1, 54.7, 50.5, 37.4, 36.8, 36.6, 31.9, 25.5.

20

#### Example 185

##### Synthesis of

##### *N*-(3,4-Difluorobenzenesulfonyl)-L-(1,1-dioxothiamorpholin-3-carbonyl)-L-4-(*N,N*-dimethylcarbamyloxy)phenylalanine *tert*-Butyl Ester

25

The title compound was prepared using the procedure described in Example 92 by substitution of the appropriate starting materials.

NMR data was as follows:

<sup>1</sup>H NMR (CDCl<sub>3</sub>): δ 7.71 (m, 2H), 7.33 (m, 1H), 7.07 (d, 2H), 6.91 (d, 2H), 6.36 (d, 1H), 4.95 (m, 1H), 4.61 (m, 1H), 4.03 (m, 2H), 3.16 (m, 2H), 3.13 (m, 4H), 3.07 (m, 1H), 2.93 (s, 9H), 1.43 (s, 9H).



### New Patent Application Postcard

Inventor: Steve J. KARLIK et al.

Appn. No.: Unassigned

Docket No.: 002010-854

Working Atty.: MMH/gjs

Date: January 26, 2004

Title: COMPOSITION FOR AND TREATMENT OF DEMYELINATING DISEASES AND PARALYSIS BY ADMINISTRATION OF REMYELINATING AGENTS

Dkt. Clerk Initials



The following was/were received in the U.S. Patent and Trademark Office on the date stamped hereon:

<input checked="" type="checkbox"/> Utility Patent Application Transmittal	<input type="checkbox"/> Executed Declaration/Power of Attorney	<input checked="" type="checkbox"/> Check for \$ 4,370.00 is enclosed
<input type="checkbox"/> Design Patent Application Transmittal	<input checked="" type="checkbox"/> Unexecuted Declaration/Power of Attorney	<input type="checkbox"/> Check for \$ _____ is enclosed
<input type="checkbox"/> Continuing Prosecution Application Request	<input type="checkbox"/> Assignment/Assignment Recordation Form Cover Sheet (PTO-1595)	<input type="checkbox"/> Charge \$ _____ to Deposit Account
<input type="checkbox"/> Continuing/Divisional Application (Rule 1.53(b)) with copy of application	<input type="checkbox"/> Submission of Certified Copy of Priority Document w/ _____ certified copy(ies)	<input type="checkbox"/>
<input type="checkbox"/> Provisional Application Cover Sheet	<input type="checkbox"/> Preliminary Amendment	<input type="checkbox"/>
<input type="checkbox"/> Provisional Application Transmittal	<input type="checkbox"/> Information Disclosure Statement Transmittal	<input type="checkbox"/>
<input type="checkbox"/> Request for Continued Examination	<input type="checkbox"/> Information Disclosure Citation (PTO-1449)	<input type="checkbox"/>
INCLUDING:	<input type="checkbox"/> Information Disclosure Statement w/ _____ document(s)	<input type="checkbox"/>
<input checked="" type="checkbox"/> Specification (pages 1 - 555 )	<input type="checkbox"/> Petition for _____ Month Extension of Time	<input type="checkbox"/>
<input checked="" type="checkbox"/> Claims (claims(s) 1 - 89 , 92 pgs.)	<input type="checkbox"/> Gen. Authorization for Petition for Ext. of Time and Pymt. of Fees	<input type="checkbox"/>
<input checked="" type="checkbox"/> Drawings (Fig(s). 1 - 18b , 25 pgs.)	<input type="checkbox"/> Patent Application Data Sheet	<input type="checkbox"/>
<input checked="" type="checkbox"/> Abstract of the Disclosure		

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### New Patent Application Postcard

Inventor: Steve J. KARLIK et al.

Appn. No.: Unassigned

Docket No.: 002010-854

Working Atty.: MMH/gjs

Date: January 26, 2004

Title: COMPOSITION FOR AND TREATMENT OF DEMYELINATING DISEASES AND PARALYSIS BY ADMINISTRATION OF REMYELINATING AGENTS

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<input type="checkbox"/> Continuing/Divisional Application (Rule 1.53(b)) with copy of application	<input type="checkbox"/> Submission of Certified Copy of Priority Document w/ _____ certified copy(ies)	<input type="checkbox"/>
<input type="checkbox"/> Provisional Application Cover Sheet	<input type="checkbox"/> Preliminary Amendment	<input type="checkbox"/>
<input type="checkbox"/> Provisional Application Transmittal	<input type="checkbox"/> Information Disclosure Statement Transmittal	<input type="checkbox"/>
<input type="checkbox"/> Request for Continued Examination	<input type="checkbox"/> Information Disclosure Citation (PTO-1449)	<input type="checkbox"/>
INCLUDING:	<input type="checkbox"/> Information Disclosure Statement w/ _____ document(s)	<input type="checkbox"/>
<input checked="" type="checkbox"/> Specification (pages 1 - 555 )	<input type="checkbox"/> Petition for _____ Month Extension of Time	<input type="checkbox"/>
<input checked="" type="checkbox"/> Claims (claims(s) 1 - 89 , 92 pgs.)	<input type="checkbox"/> Gen. Authorization for Petition for Ext. of Time and Pymt. of Fees	<input type="checkbox"/>
<input checked="" type="checkbox"/> Drawings (Fig(s). 1 - 18b , 25 pgs.)	<input type="checkbox"/> Patent Application Data Sheet	<input type="checkbox"/>
<input checked="" type="checkbox"/> Abstract of the Disclosure		

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